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Richard A. Thomas

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MCDERMOTT, WILL & EMERY

4370 LA JOLLA VILLAGE DRIVE, SUITE 700

SAN DIEGO, CA 92122

EXAMINER

SKIBINSKY, ANNA

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/611,658	Applicant(s) THOMAS, RICHARD A.	
	Examiner ANNA SKIBINSKY	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 1-30,35,36,39-43,47,48,51-53,59,60 and 62-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-34,37,38,44-46,49,50,54-58 and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 12/13/2007 have been fully considered but they are not deemed persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 31-34, 37, 38, 44-46, 49, 50, 54-58, and 61 are under examination.

Claim Election/Restriction

Claims 1-30, 35, 36, 39-43, 47, 48, 51-53, 59, 60, 62-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group and Species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on June 16, 2007.

As reiterated from the previous Office Action filed 6/14/2007, claim 43 had been erroneously omitted from the list of withdrawn claims in the previous office action. In fact, it should have been withdrawn because it is dependent from claim 42, wherein claim 42 belongs to nonelected specie F4 of the election requirement mailed 12/16/2005. Claim 43 was erroneously listed with rejected claims in the previous office action when it, should, in fact, have been withdrawn. The failure to list claim 43 as withdrawn and its inclusion with the "listings" of rejected claims was a typographical error.

With regard to claims 35 and 36, it is noted that these claims depend from claim 1 and therefore also should have been withdrawn as being directed to a nonelected invention. The examiner did not read the claim dependencies accurately and mistakenly examined claims 35 and 36 as if they depended from claim **31**. As the wrong “set” of limitations were examined, any rejection of claims 35 and 36 is necessarily incorrect, therefore the rejections of these claims are hereby withdrawn. Further, as claims 35 and 36 are, in fact, directed to nonelected subject matter, they are withdrawn from further consideration.

The examiner sincerely regrets the multiple errors and apologizes for any confusion or inconvenience to applicant.

Claim Rejections - 35 USC § 101

Claims 31-34, 37, 38, 44-46, 49, 50, 54-58, and 61 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 31-34, 37, 38, 44-46, 49, 50, 54-58, and 61 are drawn to a process for determining a nuclear packing efficiency. The process for this determining involves the application of algorithms and computations of measuring components related to distances and, manipulating data points, and therefore, involves the application of a judicial exception. Regarding inventions involving the application of a judicial exception,

Art Unit: 1631

said application must be a practical application of the judicial exception that includes either a step of a physical transformation, or produces a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims recite a practical application; i.e. recite a useful, concrete, and tangible result. See MPEP 2106, in particular, Section IV, for an explanation of a concrete, tangible and useful result.

Claims 31-34, 37, 38, 44-46, 49, 50, 54-58, and 61 do not recite a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. Examples of a “real-world result” include a physical transformation of matter, or a step of communicating the result in a TANGIBLE format to a user; e.g. by outputting or displaying the result of the method. Applicant is reminded that any amendment must be fully supported and enabled by the originally filed description.

As the claims do not recite a physical transformation of matter OR a concrete, tangible and useful result, they are not directed to statutory subject matter.

Response to Applicants

2. Applicant's arguments filed 12/13/2007 have been fully considered but they are not persuasive.

3. Applicants argue (Remarks, page 9, lines 7-14) that process includes the step of “measuring a biochemical component (BC) of the nucleus of a cell and “measuring a

Art Unit: 1631

spatial displacement of the nucleus (SDN) of the cell" and that though some aspects of the claimed method can be carried out on a computer does not change the claim from a statutory method.

4. In response, if the claimed subject matter embodies a process that can solely be carried out on a computer, it fails the three prong test of being statutory subject matter, wherein the claim must be concrete, tangible, and useful. In the instant case, of claims encompassing a computer algorithm, the claims are not TANGIBLE because there is not physical transformation of matter or a real-world tangible to a user. An example of a tangible result would be the outputting or storing of the result in a USER READABLE format. The instant claims are not tangible to a user are read on the manipulation of data. Mere data manipulation is not TANGIBLE and therefor non-statutory.

5. Applicants further argue(Remarks, page 9, lines 15-22) that the measuring step can not be performed without a cell and therefore the claimed subject matter is statutory.

6. As reiterated in the previous Office Action, one can take a picture or image of a cell, transfer, scan, etc. the image to a computer, then perform the measurements via computer. Taking a picture and/or scanning a picture into a computer is not a physical transformation of matter. Applicant is reminded that a physical step does not fulfill the requirement for a practical application; the claim must recite or result in a **physical transformation** of an article. Therefore, even if the measurements were physical, they still do not represent a physical transformation of matter as the cells themselves are not changed or physically transformed as a result of the measuring steps.

7. As the claims fail to recite either a physical transformation of matter or a concrete, tangible and useful result for the reasons previously set forth and reiterated above, the rejection is maintained.

8.

Claim Rejections - 35 USC § 112-2nd paragraph

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 56 and 58 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 56 and 58 recite “is increased major axis” and “is reduced slope of the gradient line”. It is unclear as to what a “range” of “increased major axis” is intended to be or what a “range” of a “reduced slope” is intended to be; i.e. what are the metes and bounds of these limitations over the independent claim, which recites that the geometric parameter has a RANGE. Clarification is requested.

Response to Applicants

9. Applicant's arguments filed 12/13/2007 have been fully considered but they are not persuasive.

10. Applicants (page 11, lines 1-13) have pointed to a section in the specification reciting that a “range” may be “a predefined range of NPEs for a reference population of cells, or against other cells in the sample”. The recitation of “range”, as used in the independent claim is clear. However, it is still unclear by what is meant by wherein the

geometric parameter “is increased major axis” or “is reduced slope of the gradient line”. If Applicants intend to recite that the geometric parameter is “a reduced slope” or “an increased major axis”, according to a certain range as recited in the specification, than clarification using proper grammar is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 31, 37, 38, 44-46, 49, 50, and 54-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Irinopoulou et al. (Analytical and Quantitative Cytometry and Histology, vol. 20, pages 351-357, 1998). Irinopoulou et al. was cited on the IDS 7/29/2005.

3. The instant claims recite a measuring a biochemical component (BC) and a spatial displacement of the nucleus (SDN) of the cell for a number of cells in a population, determining a data point for the BC and SDN (claim 31) on separate axes for BC and SDN, identifying at least one cluster of datapoints and determining an NPE according to a preselected geometric parameter of the cluster of datapoints. The BC, as taught by the specification includes the DNA content (specification, page 10, lines 5-8), while the SDN is the volume occupied by the nucleus (specification, page 7, lines 16-18). The nuclear packing efficiency (NPE) is then determined according to the

Art Unit: 1631

preselected geometric parameter for the cluster of data points (claims 31 and 37) that are plotted on axes with predefined range (claim 38).

4. Irinopoulou et al. teach image cytometry to measure the DNA content which is plotted on one axis of a graph against the nuclear volume of cell nuclei (page 351, col. 1, lines 1-3; and page 355, Figure 3 and col. 1, lines 17-19). The clusters of data points corresponding to the DNA content and nuclear volume are extrapolated with four regression lines, each of which have a different slope (page 355, Figure 3. The slopes are used to assess the cases of cells with hyperplasia, well and poorly differentiated carcinoma, and prostatic intraepithelial neoplasia (PIN) cells (page 354, col. 2, lines 21-24). The volume to DNA content correspondence is used to determine that the PIN case has a higher content of non-DNA molecules. This is also an indication of nuclear packing in relation to the other cases where the cells with same DNA content have a smaller nuclear volume.

5. The instant claims further recite that the cells are in the S cycle (claims 44 and 45). The cells are furthermore in a state of genetic disease (claims 49, 50 and 57) and wherein the cell phenotype is aneuploidy (claim 54) or neoplastic (claim 55).

6. Irinopoulou et al. teach the study of cells in the state of carcinoma and prostatic intraepithelial neoplasia (PIN) (Abstract) where the cells are also in diploid, triploid and tetraploid states indicating aneuploidy and the passing through cellular division and the S cycle (Figure 1 and page 354, section "Results"), as required by claims 44, 45, 49, 50, 54, 55, and 57.

7. The instant claims recite that the geometric parameter is “increasing along the major axis” for the plotted cells (claim 46, 56) or is the reduced slope of the gradient line (claim 58).

8. In Figure 3 (page 355), one major axis is the x-axis where volume is plotted. Thus, the geometric parameter which is the regression line shows a greater increase in values along the major axis, as required in claims 46 and 56. Furthermore, the gradient which comprises of the four regression lines shows a “reduced slope” for the line extrapolated through the NIP cluster as compared to the poorly differentiated carcinoma, well differentiated carcinoma, and hyperplasia regression lines, as required by claim 58.

Response to Arguments

Applicant's arguments filed 3/7/2006 have been fully considered but they are not persuasive.

Applicants argue (Remarks, page 12, lines 5-7) that the instant claims recite measuring a spatial displacement of the nucleus (SDN) of the cell, that is the volume of space that is occupied by the nucleus. Applicants further argue (Remarks, page 11, lines 25-7 and 11-14) that Irinopoulou et al. describes indirect estimates of nuclear volume by using surrogate for nuclear volume and that such a measurement reflects the volume of the DNA but not the volume of the nucleus, despite the assertion that the measurement is a measurement of nuclear volume.

In response, applicant's attention is directed to Irinopoulou et al. (page 355, Figure 3 and col. 1, lines 17-19) where he teaches that "DNA content **and the nuclear volume** of four prostate lesions **were measured**" (emphasis added by the examiner).

The "volume" is plotted on the horizontal axis of Figure 3 of Irinopoulou et al.

Furthermore, though the calculations of nuclear volume in Irinopoulou et al. and the instant application maybe different, teaching of Irinopoulou et al. are thus encompassed by the instant recitation of the claims. Applicants are reminded that the

Applicants argue that Irinopoulou et al. provides not teaching or suggestion of the recited methods for determining nuclear packing efficiency (NPE) or a cell or population of cells that recite measuring a spatial displacement of the nucleus (SDN) of the cell, and that the use of the three dimensional volume measurements on one biochemical component of the nucleus in combination with DNA content as used by Irinopoulou et al. is distinct from the claimed methods directed to measurement of NPE.

9. Irinopoulou et al. teach image cytometry to measure the DNA content which is plotted on one axis of a graph against the nuclear volume of cell nuclei (page 351, col. 1, lines 1-3; and page 355, Figure 3 and col. 1, lines 17-19). The clusters of data points corresponding to the DNA content and nuclear volume are taught (page 355, Figure 3). The volume to DNA content correspondence is used to determine that the PIN case has a higher content of non-DNA molecules. This is also an indication of nuclear packing in relation to the other cases where the cells with same DNA content have a smaller nuclear volume.

10. Furthermore in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the nuclear packing efficiency and spatial displacement of the nucleus in the instant application are different than features by the same description as taught by Irinopoulou et al.) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1631

13. Claims 31, 37, 38, 44-46, 49, 50, 54-58 and 61 are rejected under 35

U.S.C. 103(a) as being unpatentable over Irinopoulou et al. as applied to claims 31, 37, 38, 44-46, 49, 50, and 54-58 above, and further in view of Baldetorp et al. (Cytometry, 1992).

14. Irinopoulou et al. teaches the study of prostate tissue using image cytometry and plotting the DNA content of prostate cell nuclei vs. the volume of the nuclei, as set forth above. Irinopolou however does not teach this method as applied to breast tissue, as required by claim 61.

15. Baldetrop et al. however teaches the study of breast cancer cells and DNA ploidy and aneuploidy that results using DNA image cytometry (Abstract).

16. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have applied the technique taught by Irinopoulou et al. to the study of breast nuclei in breast tissue as taught by Baldetrop. One of skill in the art would have been motivated to use image cytometry as taught by both Irinopoulou et al. and Baldetorp et al. to study the DNA content to nuclei volume behavior as taught by Irinopoulou et al. (Irinopoulou et al., Figure 3) because Baldetorp et al. teach the need for methods that provide prognostic information in primary breast cancer (Abstract, lines 1-3). One of ordinary skill in the art would have a reasonable expectation of success since the breast tissue of Baldetorp et al. is also aneuploid (Baldetorp et al., Abstract), as are the cells studied in Irinopoulou et al.

Response to Arguments

Applicant's arguments filed 3/7/2006 have been fully considered but they are not persuasive.

Applicant's arguments (Remarks, page 12, lines 17-27) against the obviousness rejection of Irinopoulou et al. in view of Baldetorp et al. rely on the failure of the Irinopoulou et al. reference to anticipate independent claim 31. As such, having rebutted the arguments against Irinopoulou et al. as applied to claim 31 in the 102(b) rejection above, the arguments against Irinopoulou et al. in view of Baldetorp et al. are rebutted as well.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

17. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

18. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 31-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 and 21-23 of U.S. Patent No. 6,587, 792. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 31-34 of the instant application are verbatim identical with claims 6 and 21-23 of U.S. Patent No. 6,587, 792, except that claim 6 of the Patent recites measuring the SDN of the cell “using nuclear envelope volume”, in claim 6, step (a)(2). The “using nuclear envelope volume” is the wall of the nucleus thus equates to being the outer perimeter defining the volume of the nucleus, which is the meaning applied to SDN (specification, page 7, lines 16-18) as discussed above. Thus, both claims 31 of the instant application and 6 of the Patent describe a similar invention.

Response to Arguments

Applicant's arguments filed 3/7/2006 have been fully considered.

Applicants have requested that this rejection be held in abeyance until there is an indication of allowable subject matter.

Applicant is reminded that double patenting rejections can not be held in abeyance. Until such time as a terminal disclaimer is filed and/or the claims of the instant application have been amended to overcome the double patenting rejection, the rejection will be maintained. As no terminal disclaimer has been filed, and the claims have not been amended to distinguish them from those of the '792 patent, the rejection is maintained.

Claims Free from the Art

It is noted that claims 32-34, dependent from claim 31, which recite a measuring the NPE according to a preselected geometric parameter wherein the geometric parameter is the slope of a line passing through the local maxima of a cluster and the origin, or wherein the geometric parameter is a slope of the gradient line or the geometric parameter is selected from the group consisting of eccentricity, maximum range of the major axis, maximum range of the minor axis, standard deviation of the major axis, standard deviation of the minor axis, slope of the line orthogonal of the gradient line and perimeter are free from the art.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anna Skibinsky, PhD

/Lori A. Clow, Ph.D./
Primary Examiner, Art Unit 1631
3/3/08